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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MACNEILL, ELIZABETH

ART UNIT

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MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/724,816	Applicant(s) CLUBB, THOMAS L.	
	Examiner ELIZABETH R. MACNEILL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-36,38-48 and 50-75 is/are pending in the application.
- 4a) Of the above claim(s) 7-11,30-32,34,39-41,44,54-58,66-68,70 and 73-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,12-29,33,35,37,38,42,43,45-48,50-53,59-65,69,71 and 72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 7-11, 30-32,34, 39-41,44,54-58,66-68,70 and 73-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3 August 2006.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-6,12-29, 33, 35, 37, 38,42-43,45-48, 50-53, 59-65, 69, and 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley et al (US 6,209,673) in view of Fogarty (US 4,774,949)

Shanley teaches a catheter with a first elongate tubular body (72), a second elongate tubular body (14), an elongate member (76), and a third elongate tubular body (52). See Fig 9 and 10. (Note: in the drawings the third body is indicated as 54 but in the description as 52. Based on the description and comparison to the other embodiments, the examiner believes that the drawings are mislabeled). The expandable sheath (30) acts as a mechanical stop which can pin the guide wire to hold it in place, especially with the guide wire is being used to deliver a balloon. See Col 6 at line 40 and Col 7 lines 20-65.

Shanley does not teach that the third body has a lumen with proximal and distal openings.

Fogarty teaches a catheter for use in a branched vessel with a supporting wire (36) which has a lumen and proximal and distal openings (in order to inflate the balloon 40, Fig 5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a third body with a lumen and proximal and distal openings as taught by Fogarty in order to better secure the catheter device at the branched vessel during a surgical procedure.

As to claims 3-6,12,14-17,35,38,59,61-65,69,71 Figs 9 and 10; claims 29,33, Fig 7; claim 45-53, guidewire (50), Figs 4-8.

As to claims 18-28, Shanley is silent on the specific dimensions of the catheter.

Shanley's catheter is sized and shaped to be used in the human vasculature, and therefore must fall within certain anatomical limitations. It would have been well within the skill of one of ordinary skill in the art at the time the invention was made to use the dimensions claimed by the applicant as a matter of obvious design choice to allow the catheter to be used within the human vasculature. As to claims 13 and 60, see Fig 10, (14) has a distal taper.

Response to Arguments

4. Applicant's arguments with respect to claims 1-75 have been considered but are not persuasive. As to claims 1,36,42,43,45 and 72, applicant has amended the claims to include the mechanical stop previously found in the dependent claims. Applicant

argues that the third elongate tubular body must be permanently maintained in the first tubular body by the stop. There is nothing the claims that requires the third body to be permanently maintained in the first body. Shanley teaches that expanding the balloon sheath 30 causes the guide wire to be pinned against the vessel wall, which secures the orientation of the guide wire along the branch vessel for delivery of a balloon to the branch vessel. See Col 7. As to claims 18-28, because the claimed invention and that devices of Shanley and Fogarty are intended for use in the human vasculature, there are inherent size limitations. It would be within the skill of an ordinary worker in the art to use the claimed dimensions because of the intended use of the device.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767